

10/536545

Attorney Docket No.: 20518/51-PCT (S-8500-WO)

JC20 Rec'd PCT/PTO 26 MAY 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INTERNATIONAL APPLICATION NO.: PCT/US2004/027011
INTERNATIONAL FILING DATE: 20 August 2004 (20.08.04)
PRIORITY DATE CLAIMED: 21 August 2003 (21.08.03)
TITLE OF INVENTION: SURGICAL INSTRUMENT
APPLICANT: TYCO HEALTHCARE GROUP LP et al.

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as Express Mail in an envelope with Express Mail No. EV 303 533 421 US addressed to: MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

By: Michelle Aiello
Michelle A. Aiello

17 March 2005
Date

MAIL STOP PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ARTICLE 34 AMENDMENT

Sir:

Please enter the following Amendments to the Specification and Drawings of the above-identified PCT Application under Article 34, being filed with the Chapter II Demand herewith.

Specification: Sheets 4, 7 and 8 of the Specification are replaced by amended sheets bearing the same numbers, which are found on Substitute Sheets numbered 4, 7 and 8 appended hereto. Section callouts A-A and B-B have been replaced with 4-4 and 5-5, respectively, throughout Substitute Sheets 4, 7 and 8. The subject matter of Substitute Sheets 4, 7 and 8 are supported by the above identified PCT application and recite aspects of the disclosure that Applicant is believed to be entitled. No new matter or issues are believed to be introduced by the amendments.

10/536545

JC20 Rec'd PCTO 26 MAY 2005

Article 34 Amendment

PCT/US2004/027011

Attorney Docket No.: 20518/51-PCT (S-8500-WO)

Drawings: The section callouts in Fig. 3 have been changed from A-A to 4-4 and from B-B to 5-5. Replacement drawings were filed with the U.S. Receiving Office on 29 October 2004. The subject matter of the Replacement Drawings are supported by the above identified PCT application and recite aspects of the disclosure that Applicant is believed to be entitled. No new matter or issues are believed to be introduced by the amendments.

In view of the foregoing amendments, it is respectfully submitted that the claims of the presently pending application are believed to meet the criteria for novelty, inventive step and industrial applicability as set out in PCT Article 33(2) and (3) and are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Officer should have any questions concerning this communication, the Officer is requested to call the Applicant's undersigned attorney.

Dated: March 17, 2005

Respectfully submitted,



Mark S. Leonardo
Reg. No. 41,433
Attorney for Applicants

BROWN RUDNICK BERLACK ISRAELS LLP
Box IP, 18th Floor
One Financial Center
Boston, MA 02111
Tel: 617-856-8145
Fax: 617 856-8201

1328987 v1 -

opposed. The first and second pairs are offset 90° relative to the longitudinal axis of the handle. The plurality of longitudinal fins further includes a third and fourth separate pair of the fins that are opposed and disposed in alternate planes tangential to the outer surface of the handle. The plurality of longitudinal fins define a plurality of longitudinal grooves 5 therebetween. The grooves include guide channels that direct fluid to a proximal end of the handle.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and features of the present disclosure, which are believed to be novel, are set forth with particularity in the appended claims. The present disclosure, both as to its 10 organization and manner of operation, together with further objectives and advantages, may be best understood by reference to the following description, taken in connection with the accompanying drawings wherein:

FIG. 1 is a perspective view of a surgical instrument in accordance with the principals of the present disclosure;

15 FIG. 2 is a side cutaway view of the surgical instrument shown in FIG. 1;

FIG. 3 is a side view of the surgical instrument shown in FIG. 1;

FIG. 4 is a cross sectional view of a handle of the surgical instrument taken along lines A-A of FIG. 3; and

FIG. 5 is a cross sectional view of the handle taken along lines B-B of FIG. 3.

20 DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the surgical instrument and methods of use disclosed are discussed in terms of a medical device and, more particularly, surgical instruments for suction, irrigation, etc. having improved manipulation features. These manipulation features advantageously facilitate gripping and control during a procedure, 25 including those where bodily fluids are present, and are configured to guide the flow of fluid to prevent pooling. The surgical instrument may be used to withdraw fluids from a body cavity of a subject, for example, the surgical instrument may include a Yankauer type medical suction device having a flexible tip to facilitate accurate placement of suction for efficient removal of bodily fluids from a surgical area. The surgical instrument may also be

example, staggered, undulating, serrated, offset, non-uniform and may include openings or cavities.

Referring to FIGS. 3-5, the plurality of longitudinal fins 24 include a first fin pair 24' and a second fin pair 24'' that project radially outward from outer surface 22. Fins 24 of each pair 24', 24'' are diametrically opposed about outer surface 22. First fin pair 24' and second fin pair 24'' are disposed in a substantially relative perpendicular orientation and offset 90° relative to longitudinal axis 20 of handle 18. It is contemplated that fin pairs 24', 24'' may be offset at various angular orientations according to the particular application requirements.

10 The plurality of longitudinal fins 24 further includes a third fin pair 24''' and a fourth fin pair 24'''. Fin pairs 24''' are opposed about outer surface 22 and disposed in alternate planes tangential to outer surface 22. The tangential planes of fin pairs 24''' are substantially parallel. It is contemplated that the tangential planes may be alternately configured, such as, for example, disposed at a particular angular orientation, converging, 15 diverging, etc. It is further contemplated that fins 24 may be variously disposed about outer surface 22, for example, equidistantly spaced, radially disposed at equidistant angles, etc. It is envisioned that fins 24 may be disposed in non-pair arrangements such that the fins are not opposed.

Fins 24 facilitate manipulation of apparatus 10 and define grooves 26 therebetween, 20 that advantageously guide fluids away from handle 18. This configuration reduces fluid buildup adjacent handle 18 during a procedure and prevents potentially hazardous conditions. Reduced fluid buildup facilitates enhanced grip force and control of handle 18 and apparatus 10, as will be discussed.

Each pair of adjacent longitudinal fins 24 define a groove 26 therebetween. Grooves 25 26 define guide channels 28 that guide the flow of bodily fluids away from handle 18. As shown in FIG. 4, taken along cross-section line A-A of handle 18 in FIG. 3, fin pairs 24', 24'', 24''' define alternatively sized and configured grooves 26. Handle 18 has a first wall thickness t' and grooves 26 define a corresponding volume according to the orientation of the adjacent fins 24. For example, adjacent grooves 26 may define alternate volumes, such 30 as the volume of groove 26 (defined by fin 24'' and fin 24''') being greater than groove 26 (defined by fin 24'' and fin 24'''). It is envisioned that grooves may alternatively define uniform volumes.

As shown in FIG. 5, taken along cross-section line B-B of handle 18 in FIG. 3, which is disposed distal to line A-A on handle 18, the wall thickness of handle 18 smoothly increases to a second wall thickness t'' . The increase in the wall thickness of handle 18 correspondingly reduces the volume of grooves 26. This configuration defines a distal to proximal slope of outer surface 22. The sloping configuration directs fluid in a proximal direction from handle 18 through guide channels 28. Grooves 26 are open at the proximal end of handle 18 to allow fluid to freely drain from handle 18. It is envisioned that the radial dimension of fins 24 may increase, decrease or remain uniform along any change in wall thickness of handle 18.

It is contemplated that the wall thickness of handle 18 may have varying degrees of slope or alternatively have a stepped configuration. It is further contemplated that the wall thickness of handle 18 may be uniform or slope from a proximal to distal direction. It is envisioned that the distal ends of longitudinal fins 24 can abut the finger notch 42 portion of handle 18, or alternatively may be disposed proximal from the distal end to define a gap (not shown) for fluid drainage between longitudinal fins 24 and finger notch 42.

Adjacent fins 24 define grooves 26, which reduce the overall material requirements and weight of apparatus 10. The reduction in material of handle 18 disposes the center of mass of apparatus 10 to a position distal of handle 18. Therefore, the balance point of apparatus 10, such as, for example, the center of mass, relative to the proximal and distal end of apparatus 10, is disposed distal of handle 18. This configuration advantageously facilitates improved control of apparatus 10 during use. It is contemplated that the balance point may be disposed at various positions along the length of apparatus 10, according to the particular requirements of a medical application.

The components of apparatus 10 are fabricated from materials suitable for medical applications, such as, for example, polymeric or metals, such as stainless steel, depending on the particular catheter application and/or preference of a practitioner. Semi-rigid and rigid polymeric are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. One skilled in the art, however, will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

Apparatus 10, as shown in FIGS. 1-5 and similar to that described, is assembled, sterilized and packaged for use. For example, in a suction procedure, apparatus 10 is